Department of Labor and Industries
Office of the Medical Director
Technology Assessment Update
Intradiscal Electrothermal Therapy (IDET)

I. Introduction

Discogenic back pain may result when the ligament tissue of a vertebral disc frays allowing nerves and small blood vessels into the injury site. Intradiscal Electrothermal Therapy (IDET) is intended to address discogenic pain by using heat to contract the fibers of the disc wall, thereby closing tears. The heat may also relieve pain by cauterizing nerve endings in the disc.

IDET involves inserting a hollow needle into a painful disc. An electrothermal catheter is passed through the needle into the disc and around the outer edge of the central nucleus. Then, the wire is heated over approximately 15 minutes to a temperature of 90 degrees Celsius. (AAOS 2002)

The SpineCath/Oratec Catheter, the ArthroCare System, and the Radionics RF Disc Catheter Electrode System are available for conducting IDET. These systems all received 510(k) clearance by the Food and Drug Administration. (Tec 2002)

II. Evidence

Several studies have been conducted examining the efficacy of IDET. A search on English language articles published between August 2002 and August 2003 resulted in one randomized controlled trial and 5 case series studies. In addition, 3 case studies describing adverse events have been published.

A. Published Randomized Controlled Trials

1. Pauza tested the efficacy of IDET against a placebo intervention in a randomized trial. The study used computer-generated, random numbers to assign patients with discogenic pain to either IDET or sham treatment. Sham treatment consisted of inserting a needle into the patient's back in a procedure room. (Pauza 2003)

   Researchers determined whether a patient had discogenic pain by provoking the intervertebral disc in order to replicate the patient's pain within certain pressure ranges. The researchers also conducted CT scans to assess the presence of posterior tears of the annulus fibrosus.

   Both patient groups underwent a rehabilitation program. The program included wearing a lumbar corset for 6 weeks, participating in a spine stabilization exercise program at week 6, and progressing into an independent exercise program by week 12.

Follow-up of patients occurred at 6 months using a 10-point VAS, the SF-36, and the Oswestry Disability Scale.

For 80% power to detect a difference of 2.0 points and using a 3:2 active to control subject ratio, the study required 40 IDET patients and 27 sham therapy subjects. However, the final analysis included outcomes data for 32 (86%) IDET patients and 24 (89%) sham subjects.

Study Population: The study included subjects based on the following criteria.

Inclusion criteria	Exclusion criteria
• low back pain greater than leg pain for 6 months • failure to improve after 6 weeks of non-operative care (anti-inflammatory and analgesic medications, physical therapy, or lumbar exercise program) • low back pain exacerbated by sitting or standing and relieved by lying down • Beck Depression Scale score less than 20 • no surgical interventions within the previous 3 months • less than 20% disc height narrowing on lateral plain film radiographs	• previous lumbar spine surgery • abnormal neurological exam • radicular pain • structural deformities such as spondylolisthesis • vertebral canal stenosis • scoliosis • sequestered intervertebral disc herniations or herniations greater than 4 mm • cervical or thoracic pain greater than 2 on a VAS • rheumatoid arthritis • ambulatory dysfunction • workers' compensation, injury litigation, disability remuneration • only anterior or lateral tears or with diffuse changes in the disc

On average, the subjects' high SF-36 scores indicated that patients in both groups were not particularly disabled in general health, mental health, role emotional, or social functioning. The researchers note that patients were "reasonably healthy" with slight to moderate disability in physical functioning, as seem both on the SF-36 and on the Oswestry scale. The sample may not represent typical low back pain patients.

Results: The study maintained satisfactory blinding. Twenty-nine (78%) IDET patients and 21 (74%) of the sham group believed that they were receiving active treatment.

Scores on the SF-36 improved less than 10% in both groups with no statistically significant differences between groups.

The IDET group achieved significantly better outcomes on the Oswestry Disability Scale. In addition, IDET subjects experienced statistically significant differences for absolute change and for relative change on VAS pain scores. Much of this difference resulted from a greater proportion of sham patients deteriorating. However, a higher proportion of IDET subjects also improved more than 2 points in pain and experienced greater than 75% pain relief.

Mean Main Outcomes Scores of Patients who Underwent IDET or Sham at 6 Months

Outcome Measure	IDET (n=32)	Sham (n=24
VAS for pain (0-10)		
Pre-treatment	6.6	6.5
6 months	4.2	5.4
Change	2.4	1.1
SF-36: Bodily Pain (0-100)		
Pre-treatment	36	35
6 months	53	44
Change	17	9
SF-36: Physical Functioning (0-100)		
Pre-treatment	56	49
6 months	71	60
Change	15	11
Oswestry Disability Scale (0-100)		
Pre-treatment	31	33
6 months	20	28
Change	11	4

Per protocol analysis of changes in pain scores for patients treated with IDET or Sham

Outcome	IDET (n=32)		Sham (n=24)	
	N	%	N	%
Pain (0-10)				
Worse	2	6	8	33
Same	5	16	5	21
Improvement <2.0	7	22	2	8
Improvement >2.0	18	56	9	38

IDET has a number-needed-to-treat of 5 for achieving greater than 75% pain relief. The therapy was also more effective for patients with pain scores less than 70 and for patients with poor function or greater disability before treatment.

After omitting one sham therapy patient with outlier outcomes, the mean scores for the VAS, Bodily Pain, Physical Functioning, and Oswestry Disability scales become significantly better in favor of IDET.

Conclusion: IDET achieved a significantly greater improvement in pain scores and disability than sham treatment.

B. Randomized Controlled Trials Presented at Conferences
While several studies have been presented at conferences, only one was a randomized controlled trial.

1. In April 2003, Freeman presented findings from a randomized double-blind controlled efficacy study at the Spine Society of Australia 2003 conference in Canberra, Australia. (Freeman 2003)

A 2:1 IDET to control randomization scheme resulted in 38 subjects in the IDET group and 19 patients in the sham treatment group. In all cases, the IDET catheter was positioned under sedation to cover at least 70% of the annular tear. A technician connected the catheter to the generator and delivered energy only to the active treatment group. Both patient and surgeon were blinded to treatment.

The tools used to measure outcome include the Low Back Outcome Score (LBOS), Oswestry Index, SF-36, Zung Depression Index, and the Modified Somatic Perceptions Questionnaire. The researchers defined success as no neurological deficits, greater than 7 point improvement on the LBOS, and improvement on SF-36 subsets. Measurements were taken at 6 months.

Study population: The study included subjects with one or two level symptomatic disc degeneration with posterior or posterolateral annular tears as determined by provocative CT/discography. The study excluded subjects with greater than 50% loss of disc height or previous back surgery.

Results: No subjects from either group improved more than 7 points on the LBOS or on SF-36 subsets. Mean Oswestry scores for the IDET group were 41.4 at baseline and 39.7 at 6 months compared to 40.7 at baseline and 41.5 at 6 months for the placebo group.

Conclusion: The researchers state that the study demonstrates no significant benefit from IDET over placebo.

C. Published Case Series Studies With Comparison Groups

1. Bogduk conducted a trial examining outcomes of patients who received IDET in contrast to a comparison group. Of the 53 patients who met study criteria, insurance carriers authorized IDET for 36 patients. The 36 patients became the IDET study group, and the remaining 17 patients made up the convenience sample comparison group. The comparison group underwent a rehabilitation program involving physical therapy, strengthening and conditioning exercises, education, and counseling. (Bogduk 2002)

   The researchers used a VAS, return to work status, and patient use of opioid analgesics or other major interventions to measure outcomes. The study defined success as reducing pain by at least 50%, returning to work or activity, and not using opioids to control pain. Follow-up occurred at 3, 12, and 24 months.

   Study Population: The study included patients who had back pain for longer than 3 months and who had not responded to conservative interventions. In addition, the subjects were diagnosed with internal disc disruption. Infiltration of the disc reproduced pain, whereas infiltration of adjacent discs did not. The painful disc had to exhibit a radial fissure reaching at least the outer third of the anulus fibrosus.

Finally, the height of the disc had to be preserved to within 80% of expected normal height.

Excluded from the study were patients with severely disrupted discs or lumbar arthrodesis.

Eight of the comparison subjects and 17 of the IDET subjects received workers' compensation or were involved in motor vehicle accidents.

Results: At 3 months, the comparison group exhibited no change on median pain scores, whereas IDET subjects' median scores decreased to 3.5. At 12 and 24 months, pain scores for the comparison group were not significantly better than before treatment. However, the IDET group maintained significant improvement from baseline. Outcomes remained statistically different from the comparison group.

Median Pain Scores on a VAS of Patients who Underwent Comparison Treatment or Treatment with IDET

	Comparison		IDET	
	N	Median VAS	N	Median VAS
Before treatment	17	8.0	36	8.0
3 months	17	8.0	36	3.5
12 months	12	7.5	35	3.0
24 months	10	7.5	35	3.0

At 12 months, 10% of comparison patients and 60% of IDET patients met the criteria for success. The percentage of successful subjects in the IDET group decreased to 54% at 24-month follow-up.

Conclusion: The authors conclude that the long-term results of IDET are stable. While the therapy is not universally successful, 54% of patients may reduce their pain by half. One in five patients may expect complete pain relief.

D. Published Case Series Studies Without Comparison Groups

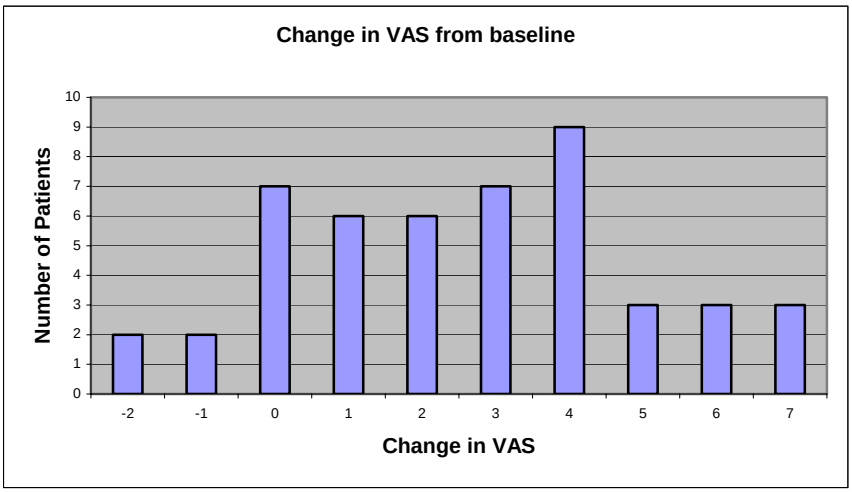
1. Endres' prospective study used a VAS, walking and sitting tolerance, and work status to measure subject outcomes at 2, 4, 6, 8, and 12-week follow-up. (Endres 2002)

   Study Population: They study group was comprised of 54 patients with a mean age of 40 years.

   The study included patients with pain lasting more than 9 months despite attempts at conservative treatment. MRI demonstrated degenerative changes, and post-discography CT demonstrated annular disruption to the outer third of the annulus.

   Patients were excluded due to disc height less than 50%, previous back surgery, spinal stenosis, and disc protrusion with neurocompressive lesion and radicular symptoms.

Results: The authors did not report the average follow-up time.



Mean Sitting and Walking Tolerances

	Pre-IDET	Post-IDET
Sitting in an automobile (n=53)	35.52 minutes	60.42 minutes
Sitting on a firm surface (n=52)	27.23 minutes	41.25 minutes
Walking (n=54)	21.39 minutes	50.00 minutes

Thirty-five patients returned to work while 18 patients did not.

Conclusion: The researchers reporting finding an increase in sitting and standing tolerances and a decrease in pain levels after IDET.

2. Gerszten conducted a prospective case series using the SF-36 and the Oswestry Disability Questionnaire to measure outcomes at 6 weeks, 3 months, and one year. (Gerszten 2002)

   Study Population: The study included 27 patients who had a mean age of 41 years and a mean duration of symptoms of 38 months. Nineteen patients received workers' compensation.

   The subjects experienced chronic low back pain for at least 6 months and failed conservative therapy. MRI provided evidence of discogenic back pain.

   Patients were excluded due to instability, infection, malignancy, or metabolic disorder.

   Results: At one year, 45% of patients reported a significant improvement on the SF-36 and 75% of patients improved on the Oswestry Questionnaire.

Outcomes Pre and Posttreatment Comparisons

Scale	Baseline	Post-Treatment	% Change
SF-36 physical function	32	47	47%
SF-36 bodily pain	27	38	41%
SF-36 role functioning-physical	5	16	220%
Oswestry questionnaire	34	30	12%
Neurogenic	15	14	7%

The researchers did not find any association between outcome and workers' compensation status.

Conclusion: The researchers conclude that IDET may be useful in patients who would otherwise undergo fusion.

3. Lutz conducted a prospective case series using a VAS for pain and lower extremity, patient satisfaction survey, and the Roland-Morris Disability Questionnaire (RMDQ) to measure patient outcomes. Researchers defined a clinically positive improvement as a change of more than 2 points on the VAS, a change of more than 2 points on the RMDQ, and a positive patient satisfaction response. (Lutz 2003)

   Study Population: The study included 34 patients with a mean age of 40 years and a mean duration of symptoms of 46 months. Fifteen subjects received workers' compensation.

   Patients experienced low back pain for at least 6 months and failed nonoperative treatment. A diskogram confirmed the level or levels of painful disks with protrusion of less than 5 mm.

   The study excluded subjects with greater than 50% disc height, greater than 5 mm disk extrusion or sequestered fragment, spinal canal narrowing, spondylolisthesis, previous spinal surgery, segmental instability, or infection.

   Results: Thirty-three subjects were available for an average 15-month follow-up.

   Outcome Measures and Average Change in Scores at Mean 15-Month Follow-up

	VAS – pain	VAS – lower extremity	RMDQ
Pretreatment	7.5	5.7	13.9
Posttreatment	3.9	2.0	6.6
Average Change	3.9	3.7	7.3

   Overall VAS improved more than 3 points in 23 (69.6%) patients. Of the 23 subjects, the VAS improved to 0 or 1 in 8 (35%) patients. In addition, 25 (77%) patients reported that they would have the same procedure again.

   Of the 8 subjects who were not working before treatment, 4 returned to work after IDET. Of the 3 subjects who were on modified duty, 2 returned to full duty.

The researchers noted that younger patients with relatively preserved disk height and discrete annular tears showed the best outcomes.

Conclusion: IDET offers a safe and minimally invasive option for carefully selected patients with chronic lumbar discogenic pain who have not responded to nonoperative care.

4. Saal's prospective case series used a 10-point VAS, sitting tolerance, and SF-36 to measure subject outcome. Follow-up occurred at 6 months, 12 months, and 24 months. (Saal 2002)

   Study Population: The study included 62 patients who failed to improve after a minimum of 6 months. The researchers defined failure to improve as persistent pain and disability, dissatisfaction with quality of life, and desire to pursue other treatment.

   The following inclusion and exclusion criteria were applied in choosing study subjects.

Inclusion criteria	Exclusion criteria
• low back pain for 6 months • failure to improve after 6 months of non-operative care (anti-inflammatory and analgesic medications, physical therapy, exercise program, or corticosteroid injections) • normal neurologic exam • negative straight leg test • MRI not demonstrating neural compressive lesion • Discogram reproducing pain at low pressurization with adjacent levels not demonstrating pain reproduction	• previous lumbar spine surgery • medical or metabolic disorder that would preclude follow-up • nonspinal condition that mimic lumbar pain • inflammatory arthritis

   Four patients were lost to follow-up after the 1-year assessment. Therefore, 58 patients comprised the final study group. The subjects had a mean age of 40.5 years and a mean duration of symptoms of 60.7 months. Twenty subjects received workers' compensation.

   Results: Patients experienced significant improvement on the VAS, SF-36 bodily pain subscale, SF-36 functioning subscale, and sitting tolerance at 6 months. However, the magnitude of improvement for the VAS did not increase significantly from 6 months to 24 months.

   No statistically significant difference in outcome between one-level and two-level cases.

Average Outcome Measures at Follow-up

Time of Assessment	SF-36 – physical function	SF-36 – bodily pain	VAS	Sitting tolerance (minutes)

Pretreatment	40.48	29.79	6.57	32.64
6 months	55.60	42.28	3.71	47.52
12 months	60.34	46.93	3.52	48.28
24 months	71.81	51.66	3.41	85.34

Of the 20 workers' compensation recipients, 83% of the patients returned to work.

One patient had an interbody fusion at 6 months.

Conclusion: A cohort of patients with discogenic low back pain demonstrated statistically significant improvement in VAS, sitting tolerance, and SF-36 scores at 2-year follow-up.

E. Complications and Adverse Event Case Studies

1. Cohen provides a report on a 29-year old male who had a history of low back pain with pain radiating into the left thigh. An MRI showed a contained L5-S1 herniated disc without nerve root impingement and a small L4-L5 disc bulge, with degenerative changes at both levels. The patient failed conservative therapy, steroid injections, and facet blocks. Thirteen months after the MRI, he had a discography and underwent IDET at L4-L5 and L5-S1. (Cohen 2002)

   Five days after IDET, the patient reported worsening low back pain, pain into the left foot, and weakening in the legs. A neurological exam showed nonfocal sensory changes. A repeat MRI showed a large, L5-S1 left paracentral herniated disc effacing the left S1 nerve root.

   One month later, the patient underwent an L5-S1 lumbar interbody fusion. Two years postoperatively, the patient remains pain free and has returned to full duty as a soldier.

2. Djurasovic presents a case study of a 28-year old man who experienced axial low back pain radiating into the thighs for 5 months. MRI showed a mildly degenerated disc at L5-S1. He failed nonsurgical care over a 2-month period. (Djurasovic 2002)

   The patient then sought treatment at another facility where he underwent at L4-L5 and L5-S1 IDET.

   Five months later, the patient presented with worsening axial lower back pain, dysthetic leg pain, and restricted range of motion. Radiographs revealed increased collapse of the L5-S1 disc when compared with films taken prior to IDET. MRI revealed significant edema in the L5 and S1 vertebral bodies and changes similar to degenerative disc disease with disc space collapse. The results suggested osteomyelitis.

An additional MRI at 6 months showed no change in the edema pattern and no change in symptoms.

The patient underwent an L5-S1 anterior interbody fusion using a femoral ring allograft combined with a posterior spinal fusion with instrumentation. Biopsies of the L5 vertebral body and L5-S1 disc revealed necrotic bone and disc material with no evidence of infection.

3. Hsia reports on a 56-year old woman who experienced chronic low back pain. During IDET at the L4-L5 and L5-S1 levels, she developed urinary retention, incontinence, loss of sensation, and weakness in the left leg. The surgeons found that the catheter had been placed inappropriately in the spinal canal. (Hsia 2000)

   Following the procedure, examination showed bilateral saddle anesthesia with diminished rectal tone and sensation over the posterior aspect of the left leg to the plantar foot surface. Left achilles tendon reflex was also absent. EMG and nerve conduction studies at 3 months showed denervation limited to S1 and S2 muscles of the left leg.

   The authors suggest that cauda equina is a potential complication of IDET.

III. Costs

IDET is estimated to cost between $7000 and $8800 and may be billed under the following codes. (Endres 2002) (Hayes 2002) (Regence 2002)

Codes	Number	Description
CPT	64999	Unlisted procedure, nervous system
HCPCS	S2370	Intradiscal electrothermal therapy (IDET), single interspace
	S2371	IDET each additional interspace

IV. Payer Systems

Several national payer systems have excluded IDET from coverage. In 2002, Australia conducted a technology assessment and made a noncoverage decisions. (CCOHTA 2003) The United Kingdom is currently in the process of inviting public comment regarding its decision not to reimburse for IDET. The public comment period will end in September 2003. (NICE 2003)

In 2000, Blue Cross Blue Shield (BCBS) of Massachusetts decided not to cover IDET for chronic low back pain, because it has not been proven in the medical literature to improve health outcomes. (BCBS MA 2000)

BCBS of North Carolina also chose not to provide coverage for IDET because IDET is considered investigational. This policy will undergo rereview in October 2003. (BCBS NC 2001) In May 2002, BCBS of Iowa and South Dakota made the same noncoverage determination. (Wellmark 2002)

Humana members are not eligible for IDET as it is considered experimental/investigational. In December 2002, Humana found that IDET was not "widely used and generally accepted as effective for the proposed use as reported in nationally recognized peer reviewed medical literature…" (Humana 2002)

The Regence Group considers IDET for the treatment of low back pain as investigational. However, Regence uses the following guidelines for individuals who would generally be considered for spine fusion.

A. Continued back pain despite a minimum 6 month period of nonoperative care to include the following:
- Evidence of an active rehabilitation program to include, on average, 4 to 6 visits of supervised physical therapy
- Oral anti-inflammatory medication
- Activity modification
- Progressive intensive exercise

B. MRI or CT scan that failed to demonstrate a neural compressive lesion and absence of clinical signs of nerve root compression

C. In addition to the clinical exam, discogram, MRI, or CT is appropriate to identify the painful disc level. A discogram is the preferred procedure. If done, the discogram should have reproduced the patient's typical back pain at low pressure at one or more levels with adjacent control measures not demonstrating pain reproduction.

D. No previous spinal fusion or failed back syndrome at the level to be treated with IDET

The April 2003 policy states that the results from published clinical series on IDET report low morbidity and low adverse outcomes compared to spine fusion. In addition, the data documenting reduction in back pain and improvement in quality of life appears to be as good or better than that of fusion. (Regence 2003)

V. Conclusion

Several studies have been conducted to examine the efficacy of IDET. While initial results from the studies are promising, the majority of data comes from small case series studies. Due to the lack of comparison groups in case series studies, the data does not conclusively show the effectiveness of IDET on improving pain and function.

One randomized controlled trial was recently published with results suggesting improvement in patient pain and function. However, the 6-month follow-up of the study does not indicate effectiveness in the longer term. Furthermore, the applicability of the study for workers' compensation is limited since the study excluded workers' compensation patients. A second randomized controlled trial presented at a conference suggested lack of benefit from IDET.

Until more randomized controlled trials with long-term follow-up are conducted and show the effectiveness of IDET, IDET remains a controversial and investigational therapy.

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Appendix A: Definitions for Classification of Evidence

Rating of recommendation	**Translation of evidence to recommendations**	**Rating of Therapeutic Article**
(note: technology assessment ratings in parentheses) A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population	Level A rating requires at least two consistent Class I studies*	**Class I:** Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required: a) primary outcome(s) is/are clearly defined b) exclusion/inclusion criteria are clearly defined c) adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias d) relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.
B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population	Level B rating requires at least one Class I study or two consistent Class II studies	**Class II:** Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-d above OR a RCT in a representative population that lacks one criteria a-d.
C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population	Level C rating requires at least one Class II study or two consistent class III studies	**Class III:** All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.**
U = Data inadequate or conflicting. Given current knowledge, treatment (test, predictor) is unproven	Studies not meeting criteria for class I-class III	**Class IV:** Evidence from uncontrolled studies, case series, case reports, or expert opinion.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria met, 2) magnitude of effect ≥5, and 3) narrow confidence intervals (lower limit >2).
***Objective outcome measurement*—an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).